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SUBJECT: U.S. GOVERNMENT OFFICIALS MEET WITH INDONESIAN
MINISTER OF HEALTH

REF: GENEVA 2507 (07)

¶1. Summary. Ambassador John Lange, Special Representative of the Secretary of State for Avian and Pandemic Influenza, and Dr. William Steiger, Special Assistant for International Affairs to the U.S. Secretary of Health and Human Services, met with Indonesian Minister of Health Siti Fadilah Supari, at her request, in Geneva, on April 2, 2008. They discussed issues related to the World Health Organization (WHO) intergovernmental process on pandemic-influenza preparedness, particularly the sharing of influenza viruses and access to vaccines and other benefits. The conversation covered possible material-transfer agreements, traceability mechanisms, a new name for the WHO Global Influenza Surveillance Network (GISN), and access to benefits that might result from the sharing of influenza viruses. Although the discussion covered familiar ground, Minister Supari introduced a specific idea that monetary benefits should flow directly to the countries that provide virus samples to the WHO network, based on a percentage of sales of commercially viable vaccines produced from those samples, a mechanism commonly known as a royalty. The meeting ended inconclusively, although the two sides did appear to share common ground on several aspects of the debate around sample-sharing. End Summary.

¶2. Ambassador John Lange, Special Representative of the Secretary of State on Avian and Pandemic Influenza, and Dr.

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William Steiger, Special Assistant for International Affairs to the U.S. Secretary of Health and Human Services (HHS), met with Indonesian Minister of Health Siti Fadilah Supari, at her request, in Geneva, on April 2, 2008. David Hohman, Health Attache at U.S. Mission Geneva, accompanied Steiger and Lange. Dr. Widjaja Lukito, Minister Supari's adviser on influenza issues; Dr. Indriyono Tantoro, an adviser to the Minister; and Cecep Herawan of the Indonesian Mission in Geneva, accompanied Minister Supari.

¶3. Steiger, who had earlier met with Minister Supari in Geneva on January 22, 2008, on the margins of the WHO Executive Board, opened by expressing appreciation both for the suggestion of the meeting and for the leadership Minister Supari has demonstrated on the issue of injecting more transparency, fairness and clarity in the system for sharing influenza viruses. Lange expressed appreciation for

Indonesian participation in the recent Sydney discussions, and noted that the WHO negotiations later in the week would be in a multilateral context. The Minister thanked the United States for agreeing to the meeting, and asked Dr. Widjaja to discuss four issues: material-transfer agreements, traceability mechanisms, a new name for the WHO global influenza surveillance network (GISN), and access to benefits that might result from the sharing of influenza viruses.

¶4. Dr. Widjaja noted the progress he believed the United States and Indonesia made in informal discussions facilitated by Australia on these issues, held from March 17-19, in Sydney. He then discussed the improvements Indonesia sees as needed to the traceability mechanism for virus samples the WHO secretariat had developed in response to a request from the WHO intergovernmental meeting (IGM) on pandemic-influenza preparedness, which last met in November 2007. Widjaja stressed countries needed a more user-friendly mechanism that provided data in real-time. He cited the Global Initiative on Sharing Avian Influenza Data (GISAID) as a possible model, and indicated he had learned more about this system at the Swiss Institute of Bioinformatics on his last visit to Geneva, in January 2008. He also suggested an effective, robust traceability mechanism might eventually make unnecessary the advisory, or oversight, group called for by the November IGM.

¶5. Turning to the subject of material-transfer agreements (MTAs), Widjaja said the IGM discussion was "stuck" on the issue of transferring seed viruses to commercial vaccine manufacturers, which would require prior, informed consent of the originating country (a familiar Indonesian priority). He agreed that countries could send viruses to WHO collaborating centers for risk-assessment purposes, and acknowledged that a standard, universal MTA was a possibility, but the elements

of such an agreement needed further work. The Minister intervened to stress that Indonesian law required that any biological sample shipped out of the country carry an MTA.

¶6. In concluding, Widjaja proposed to re-name the current Global Influenza Surveillance Network (GISN) as the "WHO Influenza Network," or "WIN," and said the terms of reference (TORs) for each element of the "WIN" (especially the WHO collaborating centers on influenza, the H5 reference laboratories, and so-called "essential regulatory laboratories," a category discussed at the Singapore Interdisciplinary Meeting and at the IGM in November 2007) needed revision.

¶7. Responding to Widjaja's points, Steiger agreed replacing "GISN" with "WIN" would likely find general acceptance, and stressed every element of the network required TORs, including the National Influenza Centers (NICS), which Widjaja had not mentioned. Steiger emphasized that the TORs must provide clear guidance for everyone involved in the network, and suggested the IGM should consider supporting the establishment of new WHO collaborating centers on influenza, particularly in developing countries, provided the institutions could meet and maintain the rigorous standards the WHO Secretariat sets for such designations.

¶8. Turning to the governance of the WHO network, Steiger suggested an advisory group might be necessary, especially in the short term, while member States and the WHO Secretariat improved the traceability mechanism. He agreed the tracking system had to be simple, fast, internet-based (with password protection), and user-friendly. He said the U.S. Government did not know whether GISAID was the right system, but stressed U.S. technical agencies were willing to look at a number of candidates. In any case, he said the scientists within the WHO influenza network, especially from affected countries, should determine their needs, and test the GISAID system and other models. Steiger said Ambassador Lange would announce at the upcoming meeting of the IGM Working Group that the United States, through HHS, would reprogram \$500,000 of a cooperative agreement already awarded to the WHO

Secretariat to support work on improving the traceability

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mechanism, including through the hiring of a dedicated project manager.

¶9. Discussing the sharing of possible benefits, Steiger stressed that well-defined benefits should be available for all countries in need, not just those who had cases of the H5N1 virus today. He said the WHO Secretariat had more work to do on developing a vaccine stockpile, which now consisted only of a pledge from GlaxoSmithKline of 50 million doses of an as-yet-unlicensed vaccine. He also pointed to the technical assistance provided by WHO member States and the WHO Secretariat on containment measures; training; non-pharmaceutical interventions, such as community-mitigation strategies; and technology transfer to improve the production of influenza vaccine in developing countries. He also said vaccine manufacturers have a voluntary responsibility to contribute to WHO-managed stockpiles, and to support safe vaccine-production capacity in developing countries, one of Secretary Leavitt's strategic goals.

¶10. Minister Supari, noting Steiger had touched on a sensitive issue, repeated her concern that vaccine manufacturers receive free material to develop vaccines but source countries do not benefit. The Minister then introduced a specific idea - she said source countries should receive a percentage of the sales of commercially viable vaccines developed from their viruses. When Steiger asked if she was talking about royalties, the minister said, "No, I do not want to touch (intellectual property)." She stressed, however, that the material provided by source countries had value, and she wanted the world community to recognize that value. (Comment: although the royalty idea is not new, we have not heard it for at least a year. When Ambassador Lange later asked Widjaja why he had not raised this at the Sydney meeting, Widjaja said he only had permission to discuss non-monetary benefits, and it was the Minister's purview to discuss monetary benefits. He also said he would not raise monetary benefits in the IGM Working Group meeting. In

previous discussions with U.S. Government officials, including with Steiger in January 2008 and with HHS Secretary Leavitt at the World Health Assembly in 2007, Minister Supari denied she was seeking royalties. End comment.)

¶11. Returning to the subject of possible material-transfer agreements, Steiger stressed there must be one, universal agreement, negotiated once, applicable to all, linked to the traceability mechanism, web-based, and that would track viruses in and out of the WHO system. He agreed that MTAs, or standard terms and conditions, should indicate the provenance of viruses, and include provisions that would recognize the contributions of scientists in source countries.

¶12. Minister Supari then asked when Steiger thought Indonesia would have its own WHO collaborating center on influenza. Saying he could not answer that question, Steiger noted the Eijkman Institute, with its laboratory certified at biosafety level three, had the potential over time to earn this designation from the WHO Secretariat.

¶13. Noting the Minister had asked him at their meeting in January why vaccine-manufacturer Baxter was not fulfilling the terms of its agreement with the Indonesian government related to the development and testing of an H5N1 vaccine, Steiger said he had learned the sticking point for the company related to indemnification. He urged the Minister to have her lawyers explore the indemnification proposal from Baxter.

¶14. In concluding the meeting, Steiger told Minister Supari that HHS Secretary Leavitt very much looked forward to his visit to Indonesia later in the month, and to meeting with President Yudhoyono, Coordinating Minister Bakrie, and her.

